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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,301	03/20/2002	Anuschirvan Peyman	146.1377	8950

20311 7590 06/17/2003

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EXAMINER	
TRUONG, TAMTHOM NGO	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,301	PEYMAN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12-31-04 (Petition Amdt)

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is a 371 of PCT/EP 00/05920 filed on 6-26-00. The preliminary amendment of 12-31-01 has been entered. Accordingly, claims 9 and 10 have been cancelled, and claim 11 has been added. No new matter is noted in the preliminary amendment.

Claims 1-8, and 11 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-4, 7, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. In claim 1, the definition of R^3 includes an alkyl group which can be "mono-unsaturated" or "poly-unsaturated".

While applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Also, see *In re Hill*, 161 F. 2d. 367, 73 USPQ 482 (CCPA 1947). Note, an

alkyl group has the formula of C_nH_{2n+1}. The standard meaning of alkyl does not permit unsaturation. In IUPAC naming system, the term "alkyl" means 'saturated' carbon chain. Thus, the provision for alkyl in R^3 being unsaturated renders the term indefinite.

b. Claim 11 recites a method of "inhibiting vitronectin binding", which is unclear if a bioassay or a treatment is claimed. If a treatment is claimed, then it is unclear what diseases are intended. Note, this claim language covers both diseases which are made better by the binding as well as those made worse by the binding. Thus, in this regard, the claim language does not represent what applicants intend.

c. Claims 2-4, 7, 8 and 11 are rejected as being dependent on claim 1, and carrying over its limitations.

d. It is noted that the claims does not adhere to the same superscript or subscript. For example, in some places R^5 and R^7 are used, then in other places R_5 and R_7. Applicant is requested to correct these typographical errors for consistency.

e. Claim 2 lacks antecedent basis for reciting "prodrugs" which is not recited in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of substituted purinyl compounds of formula I, does not reasonably provide enablement for the preparation of compounds of "3-deazapurine", "7-deazapurine", or "7-deaza-8-azapurine". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The quantity of experimentation necessary;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The breadth of the claims;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

While claim 1 allows for compounds of 'deazapurine', the specification does not provide any generic reaction scheme to make such a compound. The generic teaching on pages 35-38 pertains to substituted purinyl compounds only. The starting intermediate of formula IV is clearly a purinyl molecule. Nowhere in the preparation can one find the step for taking off a ring

nitrogen, nor can one find the step for making a 'deazapurine'. All the working examples describe the preparation of substituted purinyl compounds.

The state of the art, as evident by **Gilligan et. al.** (US 6,365,589), provides the teaching for compounds of imidazo-pyridine. However, said compounds are not the same as the 'deazapurine' intended herein.

Since no starting material is disclosed, and the removal of a ring nitrogen is not obvious to one skilled in the art, undue experimentation is inevitable.

Also, as has been ruled by the court in Genetech Inc. v. Novo Nordisk, failure to disclose any specific starting material or any condition for preparation constitutes lack of enablement, and relying on the knowledge of one skilled in the art cannot cure such deficiency in enablement (**Genetech Inc. v. Novo Nordisk**, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

3. **Scope of Enablement:** Claims 1-6, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using substituted purinyl compounds of formula (I), does not reasonably provide enablement for using compounds of 'deazapurine'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Again, the claims allow for compounds of 'deazapurine', but the specification only provides the bioassay for substituted purinyl compounds. Due to structural difference, the results

of substituted purinyl compounds cannot be extrapolated to those of 'deazapurine'. The specification does not indicate a correlation between 'purine' and 'deazapurine'. Thus, there is no evidence that 'deazapurine' has any biological activity.

Therefore, where the claimed compounds do not bear structures that are similar to known compounds having the same activity, and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 USC 112. See **In re Moureu et. al.** 145 USPQ 452. Note, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the **full scope** of the invention without 'undue experimentation'".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Tamthom N. Truong
Examiner
Art Unit 1624

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June 15, 2003